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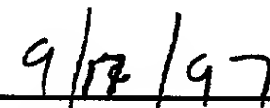
Applicant #1, Name: Eric T. Fossel
Title: Topical Delivery of Arginine to Cause Beneficial Effects

- (x) Specification, Claims, and Abstract: Nr. of Sheets 17
- (x) Declaration: Date Signed: September 17, 1997
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Very respectfully,



Signature



Date

Eric T. Fossel
17 Sunset View Road S. Hero, VT 05486

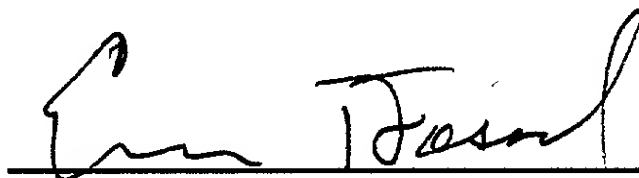


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Applicant(s): Eric T. Fossel

Appn. Title: Topical Delivery of Arginine to Cause Beneficial Effects

Examiner:

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Mailed: September 17, 1997

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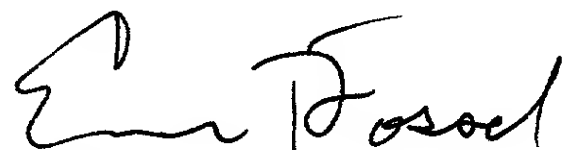
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Sir:

A disclosure document as identified below was previously filed in the Patent and Trademark Office. As this disclosure relates to the above patent application, applicant(s) request that this Disclosure Document be retained and referenced to the above application.

Disclosure Document Title: Topical Preparations of Arginine to Overcome Impotence
Disclosure Document Number: 399886
Disclosure Document Filing Date: July 9, 1996

Very Respectfully,



Signature



Date

Eric T. Fossel
17 Sunset View Road S. Hero, VT 05486

Patent Application of Eric T. Fossel
for
Topical Delivery of L-Arginine to Cause Beneficial Effects

Background

Field of the Invention

This invention relates to topical application of a cream, gel, or other vehicle which contains substances such as L-arginine which delivers these substances into tissue for the purpose of producing beneficial effects such as growth of hair on the scalp, healing of leg ulcers secondary to diabetes or confinement to bed and overcoming erectile dysfunction, as well as beneficial effects through restoration of natural mechanisms based on improvement of local blood supply.

Prior Art

Approaches to improving local blood flow have been many and consist of both systemic and topical approaches. Many beneficial effects could be obtained should improvement in local blood flow be achieved since impairment of local blood flow causes a variety of negative consequences.

It has been recognized that deficiencies in blood flow in the scalp occur in male pattern baldness. See G. Duplechain et al., *J. Louisiana State Med Soc.* **146**, 7 (1994); P Klemp et al., *J Invests Dermatol* **95**, 725 (1989); S Toshitani et al., *J Dermatol* **17**, 240 (1990). Topical minoxidil has been used as an agent for hair

growth in male pattern baldness with varying results. Though the suggestion has been made that minoxidil operates through increase in the blood supply to the scalp, many investigators have failed to show such an effect. See E de Boer et al., *Acta Dermato- Venereologica* **68**, 271 (1988); C Bunker et al., *British J Derm* **117**, 668 (1987).

It has long been recognized that impaired blood flow to the penis is a major cause of erectile failure (impotence) in men. See A Moradian et al. *Am J. Med* **85**, 748, (1988); T Hwang et al. *J Formosan Med Assoc* **89**, 992 (1990). Further it has been recognized by using isolated tissue *in vitro* and in animal experiments that nitric oxide is an important mediator of relaxation of the vessels in penile cavernous tissue. See H Kirkeby et al. *Acta Physiol Scand* **149**, 385 (1993). Topical nitroglycerine has been used in the treatment of impotence because of its ability to dilate vessels. The results were inconclusive and the treatment not well tolerated because of the cardiac response to nitroglycerine. See S Negelev *J Urology* **143**, 586 (1990).

Accordingly, several objects and advantages of the instant invention are to induce the growth of hair on portions of human scalp which has insufficient hair by means of enhancement of the body's natural mechanisms. It is yet another object of the instant invention to induce healing of superficial ulcers of the limbs by means of enhancement of the body's natural mechanisms. It is still another object of the instant invention to overcome erectile failure restoring natural male sexual function by means of enhancement of the body's own natural mechanisms.

Summary of the Invention

It was discovered that topical application of a nitric oxide precursor, L-arginine, in its various forms contained in a variety of topical preparations, either by themselves or with other agents to aid in penetration, such as a high ionic strength environment, neutralization of its charge in a complex or by other means, or included in a liposome or other biological carrier, when administered to the scalp causes hair growth, when administered to superficial ulcers causes healing and when administered to the penis enhances erectile function.

In one embodiment of the invention, a penetrating cream containing L-arginine at an effective concentration and a salt, such as sodium chloride, at a concentration sufficient to create a hostile biophysical environment for the L-arginine in the cream is applied to nightly to the scalp containing a deficit of hair induces hair growth within 3-4 months.

Further, in accordance with this invention, a penetrating cream containing L-arginine in a concentration sufficient to produce the desired effect along with sodium chloride or other salts at a concentration sufficient to produce a hostile biophysical environment when applied to the penis induces firm and natural erections within 20 minutes.

Consequently, with the discovery of the present invention, a means to restore hair

growth on a portion of scalp scarce in hair has been found. Further, with the discovery of the present invention, a means to heal superficial ulcers has been found. Additionally, with the discovery of the present invention, a means to overcome erectile dysfunction has been found.

In preferred embodiments, the delivery vehicle is a penetrating cream, the L-arginine is present as L-arginine hydrochloride in a concentration sufficient to produce the desired effect and the agent which creates the hostile biophysical environment is sodium chloride at a concentration sufficient to aid in tissue absorption.

These and other objects and features of the present invention will become apparent to those skilled in the art from reading the description of the invention, which follows.

Detailed Description of the Invention

The preferred embodiment consists of a base cream with the properties of excellent absorption into the skin which also contains L-arginine hydrochloride (12.5% w/v), choline chloride (10%), sodium chloride (5% w/v) and magnesium chloride (5% w/v). The components of the base cream may be those commonly found in hand creams, such as water, mineral oil, glyceryl stearate, squalene, propylene glycol stearate, wheat germ oil, glyceryl stearate, isopropyl myristate, steryl stearate, polysorbate 60, propylene glycol, oleic acid, tocopherol acetate, collagen, sorbitan stearate,

vitamin A & D, triethanolamine, methylparaben, aloe vera extract, imidazolidinyl urea, propylparaben, and BHA. L-arginine hydrochloride provides a precursor to the molecule, nitric oxide, NO. Nitric oxide is the substance that relaxes the blood vessels, allowing for increased blood flow. Choline chloride, sodium chloride and magnesium chloride provides a high ionic strength environment for the highly charged molecule, L-arginine. This high ionic strength environment is an example of a hostile biophysical environment for L-arginine. That is, the highly charged ionic strength is an unfavorable environment for the highly charged L-arginine making the L-arginine anxious to move to a more hospitable, less charged environment such as human tissue. The base cream containing L-arginine, choline chloride, sodium chloride and magnesium chloride is the agent which produces beneficial effects such as hair growth, healing of ulcers such as leg ulcers or restoration of normal erectile function in males suffering from erectile dysfunction..

The cream acts effectively to induce hair growth on human scalp lacking sufficient hair when applied nightly to the bald area each night for several months. Hair growth is naturally a slow process. However, substantial hair growth is achieved over large areas of scalp with results becoming evident in a few weeks and substantial within several months. Yet further, the cream acts to promote healing of superficial ulcers such as those sometimes found on the legs of persons with severe diabetes. Application twice daily for a period of two weeks causes substantial healing and in many cases complete healing is achieved within this time period or slightly longer (3-4 weeks). Still further, the cream acts to overcome erectile dysfunction in males causing restoration of natural sexual function. These applications and others share as a common mechanism of action, improvement in

local blood flow.

Other Embodiments

-Other active agents

While L-arginine hydrochloride is the preferred active agent because it is the agent in nature itself, it is non-toxic, is highly soluble and it is inexpensive, other agents could be used which are also precursors or donors of nitric oxide. These include D,L -arginine, L-arginine, alkyl (ethyl, methyl, propyl, isopropyl, butyl, isobutyl, t-butyl) esters of L-arginine and salts thereof. Pharmaceutically acceptable salts include hydrochloride, glutamate, butyrate, and glycolate.

In the case of an alternative active agent were used it would be simply substituted for L-arginine in a delivery preparation and the preparation used as in the case of the L-arginine preparation.

-Other means of effecting or improving absorption

A variety of means for effecting or improving absorption of the active agent can be envisioned. One principle behind the absorption of a highly charged molecule such as L-arginine into tissue is to either create a biophysically hostile environment in the delivery vehicle such that L-arginine would prefer to be in tissue, or to package L-arginine in such a way that it is carried into tissue or neutralize its charge by derivitization or forming a neutral salt. Examples of biophysically hostile

environments, include but are not limited to; high ionic strength by the addition of ionic salts such as sodium chloride, magnesium chloride or choline chloride; high or low pH by adding pharmaceutically acceptable acids or bases; and highly hydrophobic environments by decreasing water content and increasing lipid, oil and/or wax content. Examples of packaging which would be carried into tissue includes liposomes or emulsions of collagen, collagen peptides or other components of skin or basement membrane. Examples of neutralization of charge include delivery of the active agent in the form of an ester or salt such as arginine glutamate which is electronically neutral.

In each case of creating a hostile biophysical environment for the active agent, the agent was added to an appropriate preparation. In the case of creating a high ionic strength ions such as but not limited to sodium chloride, potassium chloride, choline chloride, magnesium chloride, lithium chloride, alone or in combination were added in high concentration. Other highly charged molecules such as polylysine, polyglutamine, polyaspartate or copolymers of such charged amino acids may be used to create the hostile biophysical environment. Alternatively a hostile biophysical environment may be created by placing the highly charged L-arginine in an hydrophobic, oily environment such as in an oil-based cream containing little or no water. Absorption may further be aided by combining the use of hostile biophysical environments with the use of penetrating agents such as oleoresin capsicum or its constituents or molecules containing heterocyclic rings to which are attached hydrocarbon chains.

Example 1

In this example a 53 year old man with a scalp lacking sufficient hair consisting of a severely receding hairline as well as large "bald spot" on the top rear of his head was provided with a penetrating cream containing L-arginine hydrochloride (12.5% w/v), choline chloride (10% w/v), sodium chloride (5% w/v) and magnesium chloride (5% w/v). The cream was applied to the bald areas each night before going to bed and was rubbed in extensively for maximal absorption. New hair growth was noted within 2-3 weeks. Within 4 months the receding hairline (previously 4 cm of bald skin) had returned to normal and the "bald spot" previously more than 7 cm in diameter had been reduced to an area of less than 2 cm with even this area showing some new hair growth.

Example 2

In a 54 year old man with a history of impotence twice daily administration of a penetrating cream containing L-arginine hydrochloride (12.5% w/v), choline chloride (10% w/v), sodium chloride (10% w/v) and magnesium chloride (5% w/v) directly to the penis twice daily for 7 days brought initial relief from the symptoms of impotence and allowed the subject to resume normal sexual activity. This relief of symptoms was maintained by continuation of the treatment daily.

Example 3

In a 62 year old man with a history of impotence placed a condom containing a water based penetrating cream containing L-arginine hydrochloride (12.5% w/v),

choline chloride (10% w/v), sodium chloride (5% w/v) and magnesium chloride (5% w/v) was worn on the flaccid penis for 30-60 minutes before erection was desired. At that time, when sexual performance was needed, an erection was easily obtained and normal sexual activity was conducted.

Accordingly, it can be seen that in the present invention I have provided agents, which when applied to scalp lacking sufficient hair causes hair growth through utilization of one of the body's own mechanisms. This effect is achieved by providing the biochemical substrate at the local site from which nitric oxide is produced. Nitric oxide causes increased local blood flow, which enables the growth of hair. Further I have provided agents which when applied to leg ulcers cause healing through use of the body's own mechanisms. Still further I have provided agents that when applied to a penis subject to erectile dysfunction causes restoration of normal sexual function. This effect is achieved by providing the biochemical substrate at the local site from which the controlling substance, nitric oxide is produced. Nitric oxide causes increases in local blood flow allowing the body's own healing cells and substances to reach the ulcer site.

Although the description above contains many specificities, these should not be construed as limiting the scope of the invention but as merely providing illustrations of some of the presently preferred embodiments of this invention. Various other embodiments and ramifications are possible within this scope.

Thus the scope of the invention should be determined by the appended claims and their legal equivalents, rather than by the examples given.

What is claimed is:

1. A method for increasing local blood flow in tissue of a mammal comprising topically administering to the mammal an effective amount of a nitric oxide precursor.
2. The method of claim 1 where the nitric oxide precursor is administered in a delivery vehicle wherein the delivery vehicle is a penetrating cream, a liquid, a lotion, an ointment or other topical preparation and wherein the nitric oxide precursor is L-arginine a salt, a complex or a derivative thereof.
3. The method of claim 2 further comprising a sufficient amount of ionic salt such as to create an ionic environment to cause absorption of the nitric oxide precursor.
4. The method of claim 2 where the delivery vehicle is a hydrophobic penetrating cream containing little or no water.
5. The method of claim 2 where the nitric oxide precursor is within a liposome or liposome like structure.
6. The method of claim 5 further comprising a sufficient amount of ionic salt such as to create an ionic strength environment within the liposome to cause tissue absorption of the nitric oxide precursor.

7. The method of claim 1 where the nitric oxide precursor is administered from a trans-dermal patch and wherein the nitric oxide precursor is L-arginine, a salt, a complex thereof.

8. The method of claim 7 where the trans-dermal patch further comprises a sufficient amount of ionic salts such as to create an ionic strength environment to cause tissue absorption of the L-arginine species.

9. The method of claim 1 where the cream consists of water (20-80%), mineral oil (3-18%), glyceryl stearate SE (0.5-12%), squalene(0.2-12%), cetyl alcohol (0.1-11%), propylene glycol stearate SE (0.1-11%), wheat germ oil (0.1-6%), glyceryl stearate (0.1-6%), isopropyl myristate (0.1-6%), stearyl stearate (0.1-6%), polysorbate 60 (0.1-5%), propylene glycol(0.05-5%), tocopherol acetate (0.05-5%), collagen (0.05-5%), sorbitan stearate (0.05-5%), vitamin A&D (0.02-4%), triethanolamine (0.01-4%), methylparaben (0.01-4%), aloe vera extract (0.01-4%), imidazolidinyl urea (0.01-4%), propylparaben (0.01-4%), bha (0.01-4%), L-arginine hydrochloride (0.25% to 25%), sodium chloride (0.25% to 25%), magnesium chloride (0.25% to 25%).

10. The method of claim 9 further comprising choline chloride (0.25-25%).

11. The method of claim 9 wherein the nitric oxide precursor is L-arginine glutamate (0.25-25%)

12. A method for overcoming impotence by applying, through means of a delivery vehicle to the penis, an effective dose of a precursor to the endothelial relaxing factor, nitric oxide.

13. The method of claim 12 where the delivery vehicle is a penetrating cream, a liquid, a lotion, and ointment or other topical preparation containing L-arginine, salt or salts of L-arginine, a complex of L-arginine or a derivative of L-arginine in an effective dose.

14. The method of claim 12 where the delivery vehicle is a penetrating cream, a liquid, a lotion, an ointment or other topical preparation containing L-arginine, salt or salts of L-arginine, a complex of L-arginine or a derivative of L-arginine in an effective dose in addition to other ionic salts such as to create an ionic strength environment high enough to provide an extra force to cause tissue absorption of the L-arginine species.

15. The method of claim 12 where the delivery vehicle is a penetrating cream of hydrophobic nature containing oils, waxes and other hydrophobic materials and little water sufficient to aid in the absorption of the nitric oxide precursor L-arginine, salt or salts of L-arginine, a complex of L-arginine or a derivative of L-arginine in an effective dose.

16. The method of claim 12 where the delivery vehicle is a penetrating cream, a liquid, a lotion, an ointment or other topical preparation containing liposomes in

which are encapsulated L-arginine, salt or salts of L-arginine, a complex of L-arginine or a derivative of L-arginine in an effective dose.

17. The method of claim 12 where the delivery vehicle is a penetrating cream, a liquid, a lotion, an ointment or other topical preparation containing liposomes in which are encapsulated L-arginine, salt or salts of L-arginine, a complex of L-arginine or a derivative of L-arginine in an effective dose in addition to other ionic salts such as to create an ionic strength environment high enough to provide extra force to cause absorption of the L-arginine species.

18. The method of claim 12 where the delivery vehicle is contained in a condom or its equivalent which contains a penetrating cream, lotion, gel, ointment or other topical preparation containing L-arginine, a salt or salts of L-arginine, a complex of L-arginine or a derivative of L-arginine in an effective dose.

19. The method of claim 12 where the delivery vehicle is contained in a condom or its equivalent which contains a penetrating cream, lotion, gel, ointment or other topical preparation containing L-arginine, a salt or salts of L-arginine, a complex of L-arginine or a derivative of L-arginine in an effective dose in addition to other ionic salts such as to create an ionic strength environment high enough to provide an extra force to cause tissue absorption of the L-arginine species.

20. The method of claim 12 where the delivery vehicle is a cream containing water (20-80%), mineral oil (3-18%), glyceryl stearate(0.25%-12%), squalene (0.2-12%),

In the United States Patent and Trademark Office

First/Sole Applicant: Eric T. Fossel

Other Applicant(s):

Title: "Topical Delivery of L-Arginine to Cause Beneficial Effects"

Small Entity Declaration - Small Business Concern

I hereby declare that I am

() the owner of the small business concern identified below:

(x) an officer of the small business concern empowered to act on behalf of the concern identified below:

Name of Concern: Strategic Science and Technologies, Inc.

Address of Concern: 17 Sunset View Road, South Hero, VT 05486

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the above entitled invention of the above applicants and the specification filed herewith.

I acknowledge a duty to file, in the above application for patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Declaration for Utility or Design Patent Application

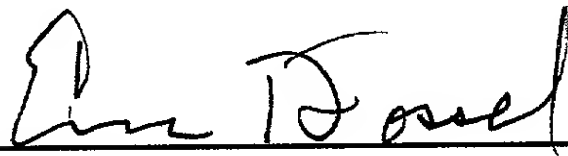
As a below-named inventor, I hereby declare that my residence, post office address, and citizenship are as stated below next to my name and that I believe that I am the original, first, and sole inventor [if only one name is listed below] or an original, first, and joint inventor [if plural names are listed below] of the subject matter which is claimed and for which a patent is sought on the invention, the specification of which is attached hereto and which has the following title:

"Topical Delivery of L-Arginine to Cause Beneficial Effects"

I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment specifically referred to in the oath or declaration. I acknowledge a duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Title 18, United States Code, Section 1001, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Please send correspondence and make telephone calls to the First Inventor below.



Signature

9/17/97

Date

Eric T. Fossel
17 Sunset View Road S. Hero, VT 05486

Resident Of: Grand Isle, VT
Citizen Of: US
Telephone: 802-372-9763

wheat germ oil (0.1-6%), cetyl alcohol (0.1-11%), propylene glycol stearate SE (0.1-11%), polysorbate 60(0.1-5%), propylene glycol (0.05-5%), vitamin E (0.02-4%), hyaluronic acid/collagen (0.05-5%), vitamin A& D (0.02-4%), sorbitan stearate (0.05-5%), triethanolamine(0.01-4%) , imidazolidinyl urea(0.01-4%), methylparaben(0.01-4%), propylparaben(0.01-4%%) , bha 0.01-4%), aloe vera extract 0.01-4%), L-arginine hydrochloride (0.25% to 25%) and sodium chloride (0.25% to 25%), choline chloride (0.25-25%) and magnesium chloride (0.25-25%).

21. A method for promoting hair growth in a mammal comprising administering to the mammal an effective dose of a nitric oxide precursor in a delivery vehicle.

22. The method of claim 21 wherein the mammal is a female and lacking sufficient hair.

23. The method of claim 21 wherein the mammal is male and lacking sufficient hair.

24. The method of claim 21 where the nitric oxide precursor is administered in a delivery vehicle wherein the delivery vehicle is a penetrating cream, a liquid, a lotion, an ointment or other topical preparation and wherein the nitric oxide precursor is L-arginine a salt, a complex or a derivative thereof.

25. The method of claim 24 further comprising a sufficient amount of ionic salt such as to create an ionic environment to cause absorption of the nitric oxide precursor.

26. The method of claim 24 where the delivery vehicle is a hydrophobic penetrating cream containing little or no water.

27. The method of claim 24 where the nitric oxide precursor is within a liposome or liposome like structure.

28. The method of claim 27 further comprising a sufficient amount of ionic salt such as to create an ionic strength environment to cause tissue absorption of the nitric oxide precursor.

29. The method of claim 21 where the nitric oxide precursor is administered from a trans-dermal patch and wherein the nitric oxide precursor is L-arginine, a salt, a complex thereof.

30. The method of claim 29 where the trans-dermal patch further comprises a sufficient amount of ionic salts such as to create an ionic strength environment to cause tissue absorption of the L-arginine species.

31. The method of claim 21 where the cream consists of water (20-80%), mineral oil (3-18%), glyceryl stearate SE (0.5-12%), squalene(0.2-12%), cetyl alcohol (0.1-11%), propylene glycol stearate SE (0.1-11%), wheat germ oil (0.1-6%), glyceryl

stereate (0.1-6%), isopropyl myristate (0.1-6%), stearyl stearate (0.1-6%), polysorbate 60 (0.1-5%), propylene glycol(0.05-5%), tocopherol acetate (0.05-5%), collagen (0.05-5%), sorbitan stearate (0.05-5%), vitamin A&D (0.02-4%), triethanolamine (0.01-4%), methylparaben (0.01-4%), aloe vera extract (0.01-4%), imidazolidinyl urea (0.01-4%), propylparaben (0.01-4%), bha (0.01-4%), L-arginine hydrochloride (0.25% to 25%), sodium chloride (0.25% to 25%), magnesium chloride (0.25-25%) and choline chloride (0.25-25%).

32. The method of claim 31 wherein the nitric oxide precursor is L-arginine glutamate (0.25-25%)

Abstract:

A preparation is disclosed for producing enhanced blood flow in tissue thus causing beneficial effects such as promoting hair growth on scalp tissue lacking sufficient hair, restoring normal sexual function in males with erectile dysfunction. Specifically, this is a preparation which provides local delivery of the amino acid L-arginine, an important biological precursor to the main substance which is responsible for relaxation of blood vessels permitting enhancement of blood flow. In the preferred embodiments, the L-arginine is provided so that it can be topically applied to the scalp or penis. The preparation also contains an agent which aids in the transfer of L-arginine into the tissue. In the preferred embodiments this agent overcomes the resistance to transfer caused by the high charge density of L-arginine. In the preferred embodiments this means is high ionic strength created by addition of choline chloride, magnesium chloride and sodium chloride. This preparation when applied nightly to scalp tissue lacking sufficient hair for a period of time causes substantial growth of hair on the scalp. Further, when applied to the penis of a subject with erectile dysfunction causes restoration of normal sexual function.